

Title: The Casein and Caseinates Regulations IA No: DEFRA1479 Lead department or agency: Defra Other departments or agencies: Food Standards Agency Scotland, Wales and Northern Ireland	Impact Assessment (IA)		
	Date: 03/05/2013		
	Stage: Final		
	Source of intervention: EU		
	Type of measure: Secondary legislation		
Contact for enquiries: Cath Harris 020 7238 2299			
Summary: Intervention and Options		RPC Opinion: GREEN	

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Measure qualifies as One-Out?
£-£0.009m	£-£0.001m	£0.0001m	Yes IN

What is the problem under consideration? Why is government intervention necessary?

As identified by the Red Tape Challenge Hospitality, Food and Drink theme, the regulatory landscape for food labelling and composition is difficult to navigate, putting unnecessary burdens on business. As part of the Government's solution to improve this, we committed to consolidate The Casein and Caseinates Regulations 1985 (S.I No 2026) and The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321) and, as far as possible, to replace the existing criminal sanctions with civil sanctions.

What are the policy objectives and the intended effects?

(i) To provide in domestic law for proportionate, effective and risk-based enforcement, in England, of certain EU obligations contained in Council Directive 83/417/EEC. This Directive concerns lactoproteins (caseins and caseinates) which are intended for human consumption and mixtures thereof.

(ii) To simplify Regulations by consolidating two SIs making referencing easier for industry and enforcers.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1 - Do nothing – continue with business as usual (the baseline).

Option 2 - Consolidate current regulations from 2 statutory instruments to 1 statutory instrument. The current regulations which apply to composition, standards and labelling would remain unchanged, but the criminal sanctions for breaching the regulations would be replaced with civil sanctions (an improvement notice regime consistent with other similar regulations for food). The only exception to this is with regard to regulation 6 of The Casein and Caseinates Regulations 1985 (which requires heat treatment of casein products). It is proposed that this remains a criminal offence as the Food Standards Agency (FSA) considers a breach of this regulation to be a potentially serious risk to human health.

Option 2 is our preferred Option.

Will the policy be reviewed? It will not be reviewed. If applicable, set review date: Month/Year					
Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	Micro Yes	< 20 Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: N/A		Non-traded: N/A

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: _____ Owen Paterson _____ Date: _____

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -0.009

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0.009	0	0.009

Description and scale of key monetised costs by 'main affected groups'

Industry

One off costs: familiarisation £1,200 (PV) (EAC £140);

Government

One off costs: familiarisation £8,000 (PV) (EAC £900)

Other key non-monetised costs by 'main affected groups'

There are no non-monetised costs associated with this Option.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised benefits by 'main affected groups'

There are no monetised benefits associated with this option.

Other key non-monetised benefits by 'main affected groups'

Industry: A more proportionate enforcement procedure for businesses

Government: Simpler enforcement procedures for enforcement officers

Key assumptions/sensitivities/risks

Discount rate (%) 3.5

Familiarisation costs

Industry - equivalent of 1 regulatory affairs/production managers per business approximately 1 hour respectively to familiarise.

Government - equivalent of 1 trading standards officer per local authority approximately 1 hour respectively to familiarise.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0.0001m	Benefits: 0	Net: £0.0001m	Yes	IN

Evidence Base (for summary sheets)

References

- The Casein and Caseinates Regulations 1985 (S.I No 2026)
- The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321)

Problem under consideration

1. One of the current Government priorities is to remove burdensome or outdated regulations where they are no longer needed. As part of the Red Tape Challenge (RTC) Exercise covering the Hospitality theme, a review of all existing rules covering food labelling and compositional standards was carried out. It was concluded that the landscape was difficult for businesses to navigate. As a result, the Government committed to merging and repealing a number of food labelling and composition regulations to reduce the regulatory burden on businesses by simplifying the regulatory landscape. There are currently two sets of Casein and Caseinates Regulations. The aim is to streamline the regulations so that there is one Statutory Instrument (SI) and, as far as possible, to replace the criminal sanctions with civil sanctions in line with the government's objectives to reduce the burdens on the industry and others such as enforcers.
2. This impact assessment analyses the options on an England only basis because food is a devolved matter.

Rationale for intervention

3. The aim is to streamline the Regulations and to reduce unnecessary bureaucracy and burdens on business. Consolidating the two SIs requires Government intervention as it is a change in secondary legislation.

Options Considered

The following Options have been considered:

4. **Option 1** – Do nothing – continue with business as usual (the baseline).
5. **Option 2** – Consolidate the current regulations from 2 SI to 1 SI. The current regulations which apply to composition, standards and labelling would remain unchanged, but the criminal sanctions for breaching the regulations would be replaced with civil sanctions (an improvement notice approach consistent with other similar regulations for food). For this option it will be the responsibility of Local Government Trading Standards officers to familiarise themselves with the new single SI, and understand the move to an improvement notice system for non-compliance with the Regulation.

Background

6. Casein is the principal protein constituent of milk, washed and dried, insoluble in water and obtained from skimmed milk. Caseinates are a product obtained by drying casein treated with neutralising agents.
7. Caseins are used in protein supplements, but also have industrial uses such as paper coating, fish bait and as a natural hardener for paint. Edible caseins have a wide range of uses (see Table 1 below).

Table 1: Edible applications of casein products¹

Bakery	Cheese products
Coffee whiteners and creamers	Confectionery
Cultured milk products, yoghurt <i>etc.</i>	High fat powders, shortenings and spreads
Ice cream and frozen desserts	Infant foods
Instant breakfasts and beverages	Meat products
Nutritional food bars	Pasta
Pharmaceuticals	Soups and gravies
Sports drinks	Whipped toppings

8. In England, the Casein and Caseinates Regulations implement the requirements of Council Directive 83/417/EEC on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption. The Regulations also lay down specifications for use of reserved descriptions, manufacturing specifications and labelling of products so as to ensure their free movement within the Community.

Current situation

9. Available information on this sector is limited. A public consultation which set out to clarify the assumptions made in this Impact Assessment received no responses. Informal consultation with industry suggests that there are no UK casein/caseinate manufacturers.

10. However, some evidence suggests that there are several UK wholesalers and distributors of caseins and caseinates. We have identified 49 UK casein and caseinate wholesalers and distributors of which 47 operate in England².

11. Of these 47 English companies, around 68 per cent are micro and small businesses, of which 4% are micro.

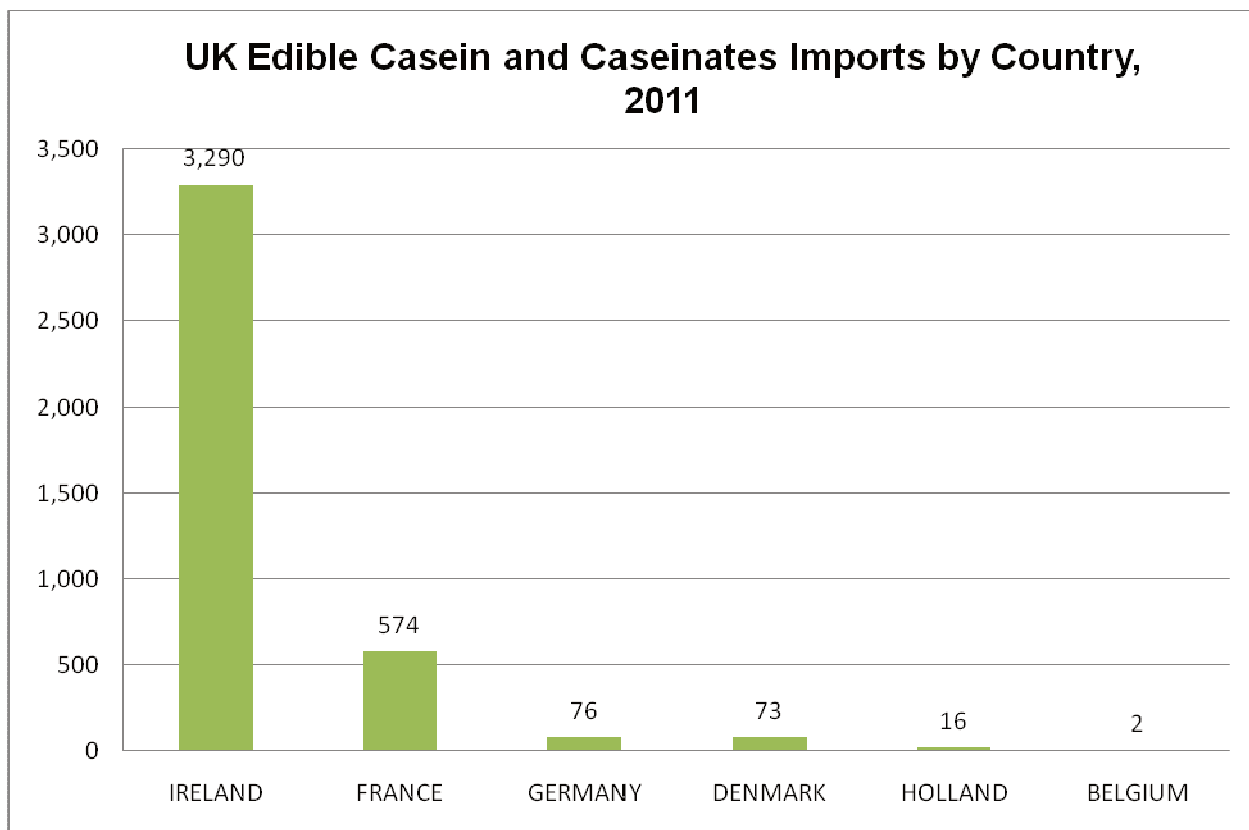
	Micro	Small	Medium	Large	Total
England	2	30	11	4	47
Wales	0	1	0	0	1
Scotland	1				1
NI	0	0	0	0	0
UK	3	31	11	4	49

12. These UK companies import casein and caseinate products from Northern Europe suppliers, predominantly Ireland and France. Indicative figures from industry suggest that in 2011, 4,032 tonnes of edible caseins were imported to the UK. Table 2 provides a breakdown imports by country³.

¹ Source: 'Casein Products' – Page 10 – <http://nzic.org.nz/ChemProcesses/dairy/3E.pdf>

² Source: Wholesale Pages and Baracel (wholesaler). This information is indicative and should be treated with caution

³ Industry contact.



Legislative framework and description of the new requirements

13. The Caseins and Caseinates (England) Regulations 2013 (“the Regulations”) will replace the following two SIs:

- The Casein and Caseinates Regulations 1985 (S.I No 2026) and
- The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321)

Both Regulations will be revoked by the proposed Regulations.

Affected Groups

14. Casein and caseinates **wholesalers and distributors** – Under Option 1, industry will not be affected. However, under Option 2, **casein and caseinates wholesalers and distributors** would be a likely to incur a one-off familiarisation cost but will also benefit from reduced enforcement burden from the consolidation of 2 SIs to 1 SI.

15. **Government** – Under Option 1, Government will not be affected. However, under Option 2, local authorities will also incur a one-off familiarisation cost whilst also benefitting from reduced enforcement burden.

16. **Consumers** – Under both Option 1 and Option 2, there is likely to be no impact on consumers. This is because there is no change to processes or products produced.

Option Appraisal

Costs and Benefits

17. Applying the 'one in two out' (OITO) methodology to the policy requirements means that the proposed consolidation of The Casein and Caseinates Regulations 1985 (S.I No 2026) and The Casein and Caseinates (Amendment) Regulations 1989 (S.I No.2321) **is subject to OITO**.
18. Although deregulatory, the proposal incurs a small net cost on business (around £1,200 PV). However as any benefits are non-monetised, this proposal is technically an 'IN'. A 6 week public consultation took place on the proposed changes between December 2012 and January 2013, however no responses were received. As we do not have any additional information with which to assess the benefits, we have filled out the summary pages on the basis of the monetised information we do have. The business assessment figures on the summary pages therefore reflect this net cost which is, in effect, negligible.

Policy Option 1 – Do Nothing (Baseline)

19. This Option would mean continuing with the current rules and would not deliver the RTC commitments.

Costs

20. There are no incremental costs associated with this Option. This is the baseline to which all other Options are compared.

Benefits

21. There are no incremental benefits associated with this Option. This is the baseline against which all other Options are appraised.

Policy Option 2 – Consolidation of 2 SIs to 1 SI

22. This Option makes for a clearer legislative environment and reduces the burden to industry and local authorities. The standardised approach to enforcement - serving an improvement notice on a trader where an authorised officer has reasonable grounds for believing that the trader has not complied with, or is unlikely to comply with, the Regulations - will be taken in the case of the Casein and Caseinates Regulations 2013 and will be consistent with other similar regulations for food composition, standards and labelling. Having been given an opportunity to put things right and having failed to do so, the draft Regulations provide that a failure to comply with the improvement notice is a criminal offence. There is no requirement for an improvement notice with regard to regulation 6 of the Caseins and Caseinates Regulations 1985: *A person must not use as an ingredient in the preparation of any casein product any casein or caseinate which has not been subjected to heat treatment at least equivalent to pasteurisation unless that casein product is itself subjected to such heat treatment during its preparation.* This is because a breach of this regulation constitutes a risk to human health, and it is therefore a criminal offence.

23. Enforcement bodies already use the improvement notice approach for a number of other Regulations. Therefore introducing this approach to the new Regulations should not create burdens. In this case it should be seen as a benefit as the sanctions in these Regulations are being brought into line with other existing proposed Regulations. It is anticipated that there will be no additional costs on an ongoing basis.

Costs

Industry

Familiarisation costs (one-off) – This cost has been monetised.

24. There will be a one-off cost to industry for reading and familiarising themselves with the new Regulations. Time will be spent acquiring, reading and understanding the legislation. Casein and

caseinate wholesalers and distributors would need to become familiar with the new requirements of The Caseins and Caseinates (England) Regulations 2013.

25. Familiarisation costs are measured in terms of time costs and are therefore quantified by multiplying the time it takes for a member of staff to read and familiarise him/herself with the Regulation by their wage rate. The wages outlined in this impact assessment represent median gross hourly pay including overtime from the Annual Survey of Household Earnings, 2011, All Employees. The relevant average hourly rate⁴ is uprated by 30% to take account of non-wage labour costs and overheads, which is in line with standard cost model methodology⁵.
26. It is assumed that **1 hour of 1 regulatory affairs/production manager's time** will be spent per business. Given these assumptions, the total one off familiarisation costs for industry in England are estimated at around £1,200 (Table 2).
27. In order for one-off costs to be compared to annual costs on an equivalent basis across the time span of the policy, one-off costs are converted into Equivalent Annual Costs (EACs) by dividing the one-off cost by an annuity factor⁶. The total one-off familiarisation cost to businesses in England translates to an equivalent annual cost of around £140 over a ten year period.

Table 2: Total familiarisation costs and Equivalent Annual Cost to Industry by Country

	Number of wholesalers and distributors	Total Familiarisation Cost	Equivalent Annual Cost
England	47	£1,193	£139
Wales	1	£25	£3
Scotland	1	£25	£3
Northern Ireland	0	£0	£0
UK	49	£1,244	£145

Government

Familiarisation costs (one-off) – This cost has been monetised.

28. Local authorities will need to become familiar with the updated Regulations for enforcement purposes. It is estimated that it would take **1 Trading Standards officer, 1 hour** to read and become familiar with the Regulations and disseminate them to key staff. The average hourly pay rate for *Inspectors of standards and regulations*⁷ is shown in the table below. This has been uprated by 30% to account for non-wage labour costs and overheads, in accordance with the standard cost model⁸.
29. Given these assumptions, the total one-off familiarisation cost to businesses in England translates to around £8,000 an equivalent annual cost of around £900 over a ten year period (Table 3).

⁴ Wage rates are obtained from ASHE 2011

⁵ <http://www.berr.gov.uk/files/file44503.pdf>

⁶ The annuity factor is essentially the sum of the discount factors across the time period over which the policy is appraised. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^j \left(\frac{1}{1+r_i} \right)$$

⁷ 2011 Annual survey of Hours and Earnings

⁸ <http://www.berr.gov.uk/files/file44503.pdf>

Table 3: Familiarisation costs for trading standards officers, by Country

	Number of Local Authorities	Median average hourly wage (uprated by 30%)	Total Familiarisation Cost	Equivalised Annual Cost
England	433	£18.01	£7,798	£906
Wales	22		£396	£46
Scotland	32		£576	£67
Northern Ireland	26		£468	£54
UK	513		£9,239	£1,073

Benefits

Industry

A more proportionate enforcement procedure for businesses - This is currently a non-monetised benefit.

30. There would be a benefit to industry in terms of moving from the current criminal sanctions regime to a new regime providing for enforcement by way of an improvement notice, followed up by a criminal offence in those cases where a improvement notice is not complied with. The only exception to this is with regard to regulation 6 (which concerns heat treatment). There is no requirement for a improvement notice with regard to this as a breach of this regulation would be a risk to human health, and therefore a criminal offence. It is anticipated that the gains will originate from reduced costs and the time saved to businesses in resolving the issues more quickly. This will materialise in the fact that the vast majority of contraventions will be resolved through the issuing of improvement notices.

31. Information provided in the food standards enforcement actions report for 2010/11 shows that there were 69 food standards prosecutions concluded in England⁹. Although it is not possible to give precise figures, the likelihood is that the number of prosecutions resulting from the contravention of The Caseins and Caseinates (England) Regulations 2013 will be extremely low or possibly none at all. We would expect the number of cases (if there are any) referred to criminal courts to be reduced. Therefore, this benefit is likely to be small or zero given the number of cases associated with caseins and caseinates is anticipated to be very small, if not zero.

Government

Simpler enforcement procedures for enforcement officers – This benefit is currently non-monetised.

32. There is a potential benefit to Government in terms of moving from the current criminal sanctions regime to the new civil sanctions regime. It is anticipated that the gains will originate from reduced court costs as the number of hearings will be reduced as issues will be resolved through issuing improvement notices, and the time saved to enforcement officers in resolving the issues more quickly instead of preparing for a court case. However, as above this benefit is likely to be relatively small or zero given the number of cases associated with caseins dealt with by enforcers are anticipated to be very small, if not zero.

Summary of monetised costs and benefits

33. Table 4 below provides a summary of the monetised costs and benefits for policy Option 2. This Option is exceptionally low cost. The Net Present Value is around -£9,000 and the Business Net Present Value is -£1,200 over the ten year period.

⁹ <http://www.food.gov.uk/multimedia/pdfs/board/fsa111108.pdf>

Table 4: Summary of costs and benefits

	Year 0	Year 1	Year 2	Year 3	Year 4
COSTS					
Industry					
Familiarisation (transition)	£1,193	£0	£0	£0	£0
Total Industry Costs	£1,193	£0	£0	£0	£0
Government					
Familiarisation (transition)	£7,798	£0	£0	£0	£0
Total Government Costs	£7,798	£0	£0	£0	£0
TOTAL COSTS	£8,992	£0	£0	£0	£0
BENEFITS					
TOTAL BENEFITS	£0	£0	£0	£0	£0
NET BENEFIT					
Total Net (Benefit)	-£8,992	£0	£0	£0	£0
Total Net Business (Benefit)	-£1,193	£0	£0	£0	£0

Year 5	Year 6	Year 7	Year 8	Year 9	Total cost/benefit	Annual Cost or Benefits/EA	PV
£0	£0	£0	£0	£0	£1,193	£139	£1,193
£0	£0	£0	£0	£0	£1,193	£139	£1,193
£0	£0	£0	£0	£0	£7,798	£906	£7,798
£0	£0	£0	£0	£0	£7,798	£906	£7,798
£0	£0	£0	£0	£0	£8,992	£1,045	£8,992
£0	£0	£0	£0	£0	£0	£0	£0
£0	£0	£0	£0	£0	-£8,992	-£1,045	-£8,992
£0	£0	£0	£0	£0	-£1,193	-£139	-£1,193

SI Consolidation

34. It is anticipated that there will be no gains to industry from SI consolidation. Gains will only be realised if existing businesses refer to the SI over the 10 year time period, or, if new businesses enter the market and save time from reading just one SI rather than two.
35. Indicative data sources¹⁰ suggest that established businesses are unlikely to refer to the SI after familiarising themselves with it unless there is a change to the legislation. Also, there were no new businesses identified in this market.
36. Given that the costs in option 2 arise from familiarisation costs associated with the SI consolidation, whilst the (non-monetised) benefits arise from a change in enforcement regime, a theoretical third option would be to keep two SIs, and just to change the enforcement regime. However, a change to only the sanctions regime would necessitate a change to the two SIs also, which would bring familiarisation costs. Therefore, option 2 is the preferred approach in lessening regulatory burden.
37. Given that a straightforward consolidation of SIs would have minimal impact, no specific group identified in the Statutory Equality Duties Impact Test would be disadvantaged.
38. A Post Implementation Review (PIR) would be disproportionate given that there would be no change in policy beyond the enforcement regime.

Conclusion

39. **Option 2 is the preferred Option** because it simplifies the regulatory landscape, although there is a negligible monetised cost. This option allows for a straightforward consolidation of 2 SIs into 1 SI as well as changes to enforcement procedures. The preferred Option is exceptionally low cost. The Net Present Value is around -£9,000 and the Business Net Present Value is -£1,200 over the ten year period. However the benefits of the consolidation and change in enforcement regime are not monetised.
40. The costs associated with this option are attributed to familiarisation costs both for industry and to local trading standards officers (one-off transition costs). The benefits are likely to originate from both industry and enforcement bodies of using improvement notices instead of criminal sanctions. The public consultation included questions to test the assumptions made, but no responses were forthcoming. Therefore, whilst these benefits are likely to be small, they may outweigh the costs of business familiarising themselves with a single SI over time.

¹⁰ Wholesale Pages and Companies House information